

K023747
NOV 15 2002

Exhibit 8

Special 510(k) Summary

Company name: Carmel Pharma AB

Product Name:

PhaSeal® - a system for closed handling of parenteral drugs.

Device name: Infusion Adapter

PhaSeal is a closed system for handling of parenteral drugs where the component devices are dedicated to each other to create the system. These single use devices are designed to promote safe handling of medications, particularly cytotoxic drugs. Leakage of drug into the environment is effectively avoided during all three phases of drug handling when the PhaSeal system is used: the preparation of the drug, the administration of the drug to the patient, and waste handling.

All drug transferring utilizes a patented double membrane technique. Each component device is sealed off with an elastomeric membrane. The membranes are joined together and transfer is made via a specially cut injection cannula. When the component devices of the system are separated after transfer, the membranes act as tight seals that prevent leakage.

PhaSeal, Infusion Adapter

The **Infusion Adapter** serves as the connecting part between the IV bag and an external IV line (e.g. IV regulators). The **Infusion Adapter** has a built in Connector which makes it possible to admix drugs into the infusion solution using the sealed PhaSeal double membrane technique.

Comparison of Predicate Devices/Equivalence

The device is substantially equivalent to previously accepted PhaSeal devices included in 510(k) Number K980381 and K001368.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 15 2002

*Mr. Kjell Andreasson
Vice President, QA/RA
Carmel Pharma AB
Box 5352
SE-402 28 Göteborg,
SWEDEN

Re: K023747

Trade/Device Name: PhaSeal®
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: November 1, 2002
Received: November 8, 2002

Dear Mr. Andreasson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

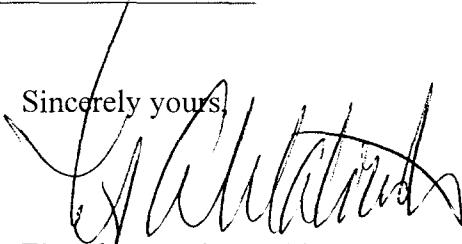
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Exhibit 3 - Indications for Use Statement

Device Name: **PhaSeal® - a System for Closed handling of Parenteral Drugs**

Infusion Adapter

The **Infusion Adapter** serves as a the connecting part between the IV bag and an external IV line (e.g. IV regulators). The **Infusion Adapter** has a built in Connector which makes it possible to admix drugs into the infusion solution using the sealed PhaSeal double membrane technique.



(Division Sign-Off)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023747